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# Lifecycle management of combination products at post-authorisation

12th meeting of the Industry Stakeholder Platform
on the operation of the centralised procedure for human medicines

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# Connected Combined Product (CCP): Medicinal product label impact

- Even when the use of the CCP is optional, **with no claimed benefits** and the CCP elements have their own instructions for use, the CPP could have a potential impact on the use of the medicinal product (quality, safety and/or efficacy). For this reason, the introduction of a CCP, generally is a type II quality variation.

- The product information should contain reference to the optional use of the medicinal product with the CCP. **No functionality claim** in the PI annexes, but only **information on availability of digital technology**.

- Specific information on use of the device (e.g. connectivity) are not acceptable in the PI annexes and should appear in the **IFU/manual guide of the App or device** only (but reference to the detailed IFU of the device/App is acceptable).

# Co-packaged (class I and IIa) devices labelling

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Co-packaged device must be in conformity with the MDR, which includes **compliance with MDR labelling requirements specific to the device** i.e.

- **Device labelling** (e.g., CE-mark, UDI, lot/serial number, manufacturer or authorised representative, ISO symbols,…) should be provided on the device itself or on its own packaging.
- **IFU** (depending on device class risk)-class I and IIa are not required IFU in accordance with Annex I, Chapter III, Section 23.1 (d) of Regulation (EU) 2017/745).

❑ Challenges flagged by Industry on the application of labelling requirements for co-packaged devices, class I and class IIa, as often provided in bulk, without own packaging and technical issues to engrave on small devices ➡ Q&A rev 4. (3.2.1) alternative solutions for **co-packaged devices I and IIa ONLY.**

❑ The product information annexes of the medicinal product including a co-packaged device must not include the labelling information of the medical device.

# Lifecycle management for integral DDCs

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**Clarifications to some aspects raised by Industry:**

- **Partial GSPR compliance identified in a NBOp is blocking for the MAA/variation**
  - EMA/CHMP cannot follow up on partial GSPR compliance issues

- **The NBOp is understood to be a "one-off" procedure (based on NB feedback)**
  - a new or revised NBOp is only required for **new device** or **major changes to the device** that may have a significant impact on the delivery or the quality, safety, or efficacy of the medicinal product.
  - The related variation/extension application should include the new/revised NBOp, in addition to the relevant supportive documentation
  - In case the device change is not considered major, a justification should be provided with the concerned variation / extension

# Lifecycle management for integral DDCs

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**Clarifications to some aspects raised by Industry:**

- **ICH Q12 principles**
  - Established Conditions are not yet reflected in EU legal framework, therefore they could not be included in the Q&A
  - Risk-based approach proposed in the MDR/IVDR Q&A as to when a NBOp is expected to be provided as part of a variation / line extension

- **A number of issues affecting EMA are under discussion with EC and NBCG-MED**

# Lifecycle management – Variations classification guideline

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- New scopes have been drafted to cover co-packed, referenced and integral devices considering the new Q&A on MDR requirements and the *Guideline on quality documentation for medicinal products when used with a medical device.*
- Effort has been made to keep the number of scopes to a minimum by keeping the wording general and focus on impact and risk rather than type of device.

- The scopes have been split on:

  - B.IV.1 Changes to device (parts) co-packaged with the medicinal product or referenced in the product information
  - B.IV.2 Changes to an integral medical device (part) {*addition, replacement, deletion, changes in design, materials, suppliers, sterilization site/process*}
  - B.IV.3 Changes to the dimensions, specification parameters and/or specification limits or analytical procedures for an integral medical device (part)

Stakeholders consultation launched until 23rd August 2024

# Thank you for your attention

## Further information

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